

*By
critic*

*Sgt
D1*

at least 50 mg arachidonic acid;
at least 200 mg phospholipids;
at least 200 µg folate;
at least one of at least 0.2 mg hypericin and at
least 500 mg Withania somnifera extract;
at least 100 mg magnesium;
at least 5 mg zinc;
at least 2 mg vitamin B6;
at least 2 µg vitamin B12; and
at least 1.0 g citrate.--

REMARKS

The claims previously in the case have been replaced by a set of new claims that are believed to be proper as to form and clearly patentable over the cited references.

In preparing the new claims, careful attention was paid to the Examiner's criticisms of the form of the original claims, all of which criticisms are believed to be satisfied by the new claims.

Reconsideration is accordingly respectfully requested, for the rejection of the claims as unpatentable over the various combinations of references that will be identified as follows:

- D1 - Sagami Chem. Res. Centre (JP 10017475-A)
- D2 - Horrobin (EP 713653),
- D3 - Hashim (WO 95/15750),

D4 - Sauvage (US 5,401,730)
D5 - Bozoky (HU 214625)
D6 - Ponomareva (SU 1837887)
D7 - Cade (WO 89/02737)
D8 - Ogawa (JP 07278000)
D9 - Bland (US 5,922,704), and
D10 - Cavazza (US 5,753,703)
D11 - Yanai (JP 10165119)
D12 - He (CN 1235770A)
D13 - Brigham (WO 97/39759)
D14 - Bridgeman (US 6,200,607)
D15 - Sakai et al. (US 5,965,413)

None of these references, nor any proper combination thereof, discloses the subject matter now claimed, for the following reasons:

D1 is directed to the combination of a phospholipid such as phosphatidylcholine or phosphatidylserine and DHA for the prevention and treatment of vascular diseases. As to the treatment of depression or its specific related disorders, D1 is silent.

D2 relates to fruit juice enriched with polyunsaturated fatty acid (GLA, DGLA, EPA) for a diversity of treatment ranging from vascular disease to skin disorder. However, there is no disclosure nor hint in D2 that such ingredients could be used for treating depression.

D3 relates to the treatment of vascular diseases by combining vitamin B6 with lecithine. No mention is made of depression or of its specific related disorders.

D4 relates to the combination of aspirin with citric acid together with zinc for treating cardiovascular diseases. As to the mention of the combination or of its use for treating depression, D4 is silent.

D5 relates to an herbal tea mixture for lowering cholesterol levels by means of a composition comprising St. John's wort. Again, there is no mention of depression.

D6 relates to herbal mixture for reducing arterial blood pressure, in which said mixture contains St. John's wort. As for D5, there is no mention of depression.

D7 relates to the use of tryptophan for treating hypertension as well as atherosclerosis. No mention is made of depression.

D8 relates to the combination of E.coli with tryptophan as a hyperlipemia therapeutic agent. This document does not suggest depression.

D9 provides omega fatty acids of the omega 3 and 6 types in conjunction with vitamins, minerals and other nutrients for reducing coronary heart disease. In D9 (col. 5 soft Gel capsule), the level of DHA+EPA+GLA is of 287.5 mg, thus far below the minimum limit now claimed of at least 350 mg. Further, there is no hint in D9 that this could be used for depression.

D10 provides a combination of alkanoyl-L-carnitines with omega 3 fatty acid for the prevention and treatment of disorders ranging from cardiovascular disorders

to tissutal disorders. However, depression or even its specific related disorders are neither disclosed or taught in D10.

D11 is a prior art document relevant for the dependent claims only. Hence, D11 is directed to the use of ginkgo tea for preventing and curing vascular disease but there is no teaching in D11 whatsoever about the prevention or treatment of depression or of its related disorders.

D12 relates to a ginkgo tea for preventing and curing vascular diseases. No mention is made of depression.

D13 relates to omega-3 fatty acids as well as "omega-3 phosphatidylcholines", i.e., esterified compounds, for treating bipolar disorder. However, there is nothing in D13 that teaches to combine omega 3 fatty acid with omega 6 fatty acid, let alone this combination with phospholipids and a compound which is a factor of methionine metabolism, for treating depression or its related disorders.

D14 relates to pharmaceutical composition comprising tyrosine and an iron compound for treating Parkinson's disease or depression. This document is relevant for the dependent claims but does not suggest the claimed combination.

D15 relates to a process for producing phosphatidylserines having long chain unsaturated fatty acid as side chain for the treatment of Parkinson's disease and dementia. This document relates to a modified phosphatidyl serine, but there is no teaching in D15 that would lead to

combine such compound with LCPUFA and/or a compound which is a factor of the methionine metabolism.

Thus, none of the above prior art teaches the combination of a compound of fraction a) with a compound of fraction b) and a compound of fraction c), let alone for the prevention and/or treatment of depression or of its specific related disorders nor do these references give us a hint that depression or its specific related disorders should be linked with cardiovascular disorder. In this respect, one skilled in the art would not make the link between cardiovascular disorder and depression. Indeed, patients suffering from cardiovascular disorder are not automatically suffering from depression. To the contrary, it appears that they generally suffer from one of the disorders but not all of them. Thus, it would not be a logical step for a skilled person to use ingredients known in the field for treating cardiovascular disorder, for preventing and/or treating depression or its specific related disorders.

As the claims now in the case clearly bring out these distinctions with ample particularity, it is believed

KILIAAN et al. S.N. 09/899,922

that they are all patentable and reconsideration and allowance are respectfully requested.

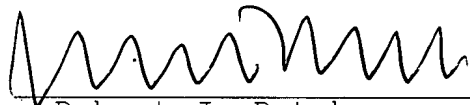
Attached hereto is a marked-up version of the changes made to the specification by the current amendment.

The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,

YOUNG & THOMPSON

By



Robert J. Patch
Attorney for Applicants
Registration No. 17,355
745 South 23rd Street
Arlington, VA 22202
Telephone: 703/521-2297

June 10, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Page 12, the first full paragraph was amended as follows:

--In another preferred embodiment the preparation additionally contains a component with anti-oxidant properties. Preferably the antioxidant is selected from the group consisting of vitamin C, vitamin E, lipoic acid, selenium salts and carotenoids. Another component which may advantageously be included in the present preparation is extract of [gingko] ginkgo biloba. This extract is obtained from the leaves and is enriched in flavonoids and especially terpenoids, in particular ginkgolides. It appears for example that an extract that comprises at least 4% ginkgolides is effective.--

Page 14, the paragraph beginning at line 8, was amended as follows:

--Example 1

Capsule for use (three times a day) by persons suffering from vascular disorders, in particular those that also suffer from secondary depression.

The capsule is prepared using methods known in the art and comprises as active components:

DHA	50 mg
EPA	75 mg

phospholipids*	250 mg
folic acid	200 µg
vitamin B12	25 mg
Hypericine	2.5 mg
vitamin B1	100 mg
[coenzym] <u>coenzyme</u> Q10	10 mg
vitamin E	200 mg
[Ginkgo] <u>Ginkgo</u> biloba	120 mg

* phosphatidylcholine 130 mg, phosphatidylserine 120 mg
(synthetic)--

Page 15, the paragraph beginning at line 10 was
amended as follows:

--**Example 3**

Muesli-bar of about 25 g based on sugar, cereals and
pieces of dried fruit that comprises as active components:

soylecithin*	2 g
encapsulated fish oil	0.6 g
Single Cell Oil (Mortierella)	0.3 g
Folic acid	400 µg
pyridoxamine	3 mg
cyanocobalamine	5 µg
zinc oxide	30 mg
magnesium oxide	200 mg
citric acid/citrate pH 6.5 mixture	2 g
Hypericum perforatum extract#	700 mg
[Ginkgo] <u>Ginkgo</u> biloba extract	200 mg
calcium sulphate	300 mg
vitamin D	10 µg

*phosphatidylcholine:phosphatidylethanolamine:

phosphatidylinositol = 45:26:14)

extract standardised to 0.3 wt.% hypericine content--